Amendments to the Specification

Please replace the entire Abstract with the following NEW ABSTRACT:

Clinical trials are defined, managed and evaluated according to an overall end-to-end system. The ~~central authority creates protocol meta-models and makes them available to clinical trial~~ protocol ~~designers. Each meta-model includes a short list of preliminary patient eligibility attributes which are appropriate for a particular disease category. The protocol designer chooses the appropriate meta-model, and~~designer encodes the clinical trial protocol, including eligibility and patient workflow, within ~~the~~a selected protocol meta-model. The resulting protocol database is stored together with databases of other protocols in a library of protocol databases. Sponsors and individual clinical sites have controlled access to the protocols. Study sites make reference to the pertinent protocol databases to which they have access in the protocol database library in order to perform patient eligibility screening. Once a patient is enrolled into a study, the protocol database indicates to the clinician what patient and data management tasks are to be performed at each patient visit. ~~These tasks can include both patient management tasks and data management tasks.~~ The workflow graph advantageously also instructs the proper time for the clinician to obtain a patient's informed consent. ~~The system reports patient progress to study sponsors, who can then monitor the progress of the trial, and to a central authority which can then generate performance metrics.~~ Advantageously, a common controlled medical terminology database is used by all components of the system.